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BY FAX (612-6285-3929) & MAIL

Attn: Mr Matthew Forward

Dear Sirs

MERLIN MD PTE LTD
PCT INTERNATIONAL APPLICATION NO. PCT/SG2004/000319
"IMPLANTABLE MEDICAL DEVICES WITH GOOD VISIBILITY AND MECHANICAL PROPERTIES"

We enclose the duly completed PCT Demand, the Fee Calculation Sheet, response to the Written Opinion, amended claims and our draft for the sum of AU$768.00 for your attention.

Under Rule 69(1)(a) we request the examination of this application commence immediately.

Kindly acknowledge receipt of the same.

Yours faithfully

Sheena Jacob
Patent Agent
ALBAN TAY MAHTANI & DE SILVA

Encl.

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We refer to the International Search Report of 9 December 2004.

We submit an amended set of claims to overcome the examiner's objection. Specifically, claim 9 has been incorporated into claim 1.

Also, we submit that none of the cited document discloses a stent made from an alloy selected from the group of platinum alloy in the specific % composition as defined in claim 1 of the present invention. WO98/14137 discloses "the alloy comprises about 90 wt % Pt and 10 wt % Ir" at page 7 line 5. However, this does not anticipate the present invention.

The selection of the present invention advantageously provides an ultimate tensile strength to the stent greater than if it were made from stainless steel. This is not suggested or taught by the prior art. The ultimate tensile strength comparison is illustrated at Table 1 on page 11 of the description. Consequently, this enables the wall thickness of the stent to be reduced. Advantageously, a reduced wall thickness allows stents with a low profile to be deployed which improves manoeuvrability. Notwithstanding the excellent mechanical properties, the selection enables enhanced visibility and biocompatibility of the stent that are highly desired for intracranial deployment use. Therefore the present invention produces an unexpected and unobvious result due to the selection of % of the platinum alloy components defined in claim 1. Hence, the claims of the present invention are now clearly distinguishable from the cited documents.

We look forward to receiving a favourable Written Opinion in due course.

Yours faithfully

Sheena Jacob
Patent Agent
ALBAN TAY MAHTANI & DE SILVA

Encl. – with confirmation copy

WE CLAIM:

1. A stent for insertion into a bodily vessel for treatment of an aneurysm or ischemic diseases,

wherein the stent is made from a platinum alloy selected from the group consisting of platinum:iridium alloy, platinum:tungsten alloy, platinum:rhodium:ruthenium alloy, platinum:rhodium alloy and platinum:nickel alloy; and

wherein the platinum:iridium alloy has a composition of about 70-80% of platinum and 20-30% iridium.

2. The stent according to claim 1, wherein the stent comprises a generally tubular structure having an exterior surface defined by a plurality of interconnected struts having interstitial spaces therebetween, said generally tubular structure expandable from a first position to a second position, wherein said tubular structure expands radially outwardly to the second position such that the exterior surface of said structure engages with the inner surface of the bodily vessel so as to maintain a fluid pathway through said bodily vessel.

3. The stent according to claim 1, wherein the stent is a self-expandable stent.

4. The stent according to any one of claims 1 to 3, wherein the platinum:tungsten alloy has a composition of about 85-95% of platinum and 5-15% of tungsten.

5. The stent according to claim 4, wherein the platinum:tungsten alloy has a composition of about 90-95% of platinum and 5-10% of tungsten.

6. The stent according to claim 1, wherein the platinum:rhodium:ruthenium alloy has a composition of about 70-85% of platinum, 10-20% of rhodium and 3-10% of ruthenium.

7. The stent according to claim 6, wherein the platinum:rhodium:ruthenium alloy has a composition of about 75-80% of platinum, 12-18% of rhodium and 5-10% of ruthenium.

8. The stent according to claim 1, wherein the platinum:rhodium alloy has a composition of about 60-80% of platinum and 20-40% of rhodium.

9. The stent according to claim 8, wherein the platinum:rhodium alloy has a composition of about 65-75% of platinum and 25-35% of rhodium.

10. The stent according to claim 1, wherein the platinum:nickel alloy has a composition of about 80-90% of platinum and 10-20% of nickel.

11. The stent according to claim 10, wherein the platinum:nickel alloy has a composition of about 85-90% of platinum and 10-15% of nickel.

12. The stent according to claim 1, wherein the stent is made from a wire of platinum:tungsten, platinum:iridium alloys, and welded to a predetermined tubular mesh.

13. The stent according to any one of claims 1 to 12, wherein the stent has a sidewall thickness of less than 0.0035".

14. The stent according to any one of claim 1 to 13, wherein the surface of the stent is modified by passive coatings.

15. The stent according to claim 14, wherein the coating is iridium oxide or titanium nitrate.

16. The stent according to claim 14, wherein the stent is coated with an external layer containing a pharmaceutically effective amount of therapeutic substances.

17. The stent according to claim 1, further comprising markers to enhance visibility and radiopacity of the device.

18. The stent according to claim 17, wherein the markers include end markers or center markers.

19. An implantable endovascular device for insertion into a bodily vessel to treat ischemic and hemorrhagic stroke, the device comprising:

a wire structure made from a platinum alloy selected from the group consisting of platinum:iridium alloy and platinum:tungsten alloy, the structure being expandable from a first position to a second position, and said structure expands radially outwardly to the second position such that an exterior surface of said structure engages with the inner surface of the bodily vessel so as to maintain a fluid pathway through said bodily vessel;

wherein the wire structure is formed by welding tubular shaped wire sections together and the exterior surface of the wire structure is defined by the welded wire sections;

wherein the device is longitudinally flexible, the flexibility being such that it is greater than a delivery catheter to deliver the device into the bodily vessel; and

wherein the longitudinal flexibility of the device is defined by deflection of the device from a neutral line to 1mm when there is a force less then 8 grams.

20. The device according to claim 19, wherein the welding is laser welding.

21. A delivery system for inserting a device an implantable medical device according to claim 1, within a bodily vessel, wherein the device is expandable by balloon inflation, the delivery system comprising a balloon delivery catheter and the device, wherein the expandable medical device is mounted onto the balloon of the delivery catheter.

22. A delivery system for inserting an implantable medical device according to claim 1, within a bodily vessel, wherein the device is self-expandable, the delivery system comprising a delivery catheter and the device, wherein the device is mounted onto a distal portion of the delivery catheter.

23. The device according to claim 19, wherein the device is deployed at a pressure equal to or below 4atm.

24. The device according to claim 19, wherein the structure of the device provides a normalized radial force 18 to 19grams per mm of length.

25. The device according to claim 24, wherein the structural support of the device provides 3 to 4% of deflection of the structure of the device together with natural pulsing of an intracranial vessel wall.

26. The device according to claim 19, wherein the device has a profile in a compressed delivery form of 0.020 inches.

27. The device according to claim 19, wherein the device has a profile between 0.014 to 0.016 inches and the profile of the device in an uncompressed delivery form is between 0.020 to 0.022 inches.

28. The device according to claim 19, wherein the device has uniform material distribution and wall coverage for providing support to a bodily vessel.

29. The device according to claim 18, wherein the ratio of the material is in the range of 12 to 16%, the range being dependent on the diameter of deployment.

30. The device according to claim 19, wherein the device comprises struts, the struts having a thickness and width less than or equal to 0.0028 inches.

31. The device according to claim 19, wherein the device has a surface to length ratio between 1.1 to 1.3mm²/mm to provide minimal vessel injury score.

WE CLAIM:

1. ~~An implantable medical device~~stent for for treatment of an aneurysm or ischemic diseases, ~~insertion into a passage,~~

wherein the ~~device~~ stent is made from a platinum alloy selected from the group consisting of platinum:iridium alloy, platinum:tungsten alloy, platinum:rhodium:ruthenium alloy, platinum:rhodium alloy and platinum:nickel alloy; and

wherein the platinum:iridium alloy has a composition of about 70-80% of platinum and 20-30% iridium.

~~2. The device according to claim 1, wherein the device is an expandable device.~~

~~3. The device according to claim 2, wherein the expandable device is a stent.~~

~~4. The device according to claim 3, wherein the passage is a bodily vessel.~~

~~5~~2. The ~~device~~ stent according to claim 41, wherein the stent comprises a generally tubular structure having an exterior surface defined by a plurality of interconnected struts having interstitial spaces therebetween, said generally tubular structure expandable from a first position to a second position, wherein said tubular structure expands radially outwardly to the second position such that the exterior surface of said structure engages with the inner surface of the bodily vessel so as to maintain a fluid pathway through said bodily vessel.

~~6~~3. The ~~device~~ stent according to claim ~~3~~1, wherein the stent is a self-expandable stent.

~~7. The device according to any one of claims 1 to 6, wherein the platinum:iridium alloy has a composition of about 60-90 % of platinum and 10-40% of iridium.~~

~~8. The device according to claim 7, wherein the platinum:iridium alloy has a composition of about 70-90% of platinum and 10-30% iridium.~~

~~9. The device according to claim 8, wherein the platinum:iridium alloy has a composition of about 70-80% of platinum and 20-30% iridium.~~

~~10~~4. The ~~device~~ stent according to any one of claims 1 to ~~6~~3, wherein the platinum:tungsten alloy has a composition of about 85-95% of platinum and 5-15% of tungsten.

~~115~~. The ~~device~~ stent according to claim ~~104~~, wherein the platinum:tungsten alloy has a composition of about 90-95% of platinum and 5-10% of tungsten.

~~126~~. The ~~device~~ stent according to ~~any one of~~ claims ~~1 to 6~~, wherein the platinum:rhodium:ruthenium alloy has a composition of about 70-85% of platinum, 10-20% of rhodium and 3-10% of ruthenium.

~~137~~. The ~~device~~ stent according to claim ~~126~~, wherein the platinum:rhodium:ruthenium alloy has a composition of about 75-80% of platinum, 12-18% of rhodium and 5-10% of ruthenium.

~~148~~. The ~~device~~ stent according to ~~any one of~~ claims ~~1 to 6~~, wherein the platinum:rhodium alloy has a composition of about 60-80% of platinum and 20-40% of rhodium.

~~159~~. The ~~device~~ stent according to claim ~~148~~, wherein the platinum:rhodium alloy has a composition of about 65-75% of platinum and 25-35% of rhodium.

~~1610~~. The ~~device~~ stent according to ~~any one of~~ claims ~~1 to 6~~, wherein the platinum:nickel alloy has a composition of about 80-90% of platinum and 10-20% of nickel.

~~1711~~. The ~~device~~ stent according to claim ~~1610~~, wherein the platinum:nickel alloy has a composition of about 85-90% of platinum and 10-15% of nickel.

~~1812~~. The ~~device~~ stent according to claim 1, wherein the ~~device~~ stent is made from a wire of platinum:tungsten, platinum:iridium alloys, and welded to a predetermined tubular mesh.

~~1913~~. The ~~device~~ stent according to any one of claims 1 to ~~1812~~, wherein the ~~device~~ stent has a sidewall thickness of less than 0.0035".

~~2014~~. The ~~device~~ stent according to any one of claims ~~1~~ to ~~1913~~, wherein the surface of the ~~device~~ stent is modified by passive coatings.

~~2115~~. The ~~device~~ stent according to ~~20~~claim 14, wherein the coating is iridium oxide or titanium nitrate.

~~2216~~. The ~~device~~ stent according to claim ~~2014~~, wherein the ~~device~~ stent is coated with an external layer containing a pharmaceutically effective amount of therapeutic substances.

~~23~~17. The ~~device~~ stent according to claim 1, further ~~comprises~~ comprising markers to enhance visibility and radiopacity of the device.

~~24~~18. The ~~device~~ stent according to claim ~~23~~17, wherein the markers include end markers or center markers.

~~25~~19. An implantable endovascular device for insertion into a bodily vessel to treat ischemic and hemorrhagic stroke, the device comprising:

a wire structure made from a platinum alloy selected from the group consisting of platinum:iridium alloy and platinum:tungsten alloy, the structure being expandable from a first position to a second position, and said structure expands radially outwardly to the second position such that an exterior surface of said structure engages with the inner surface of the bodily vessel so as to maintain a fluid pathway through said bodily vessel;

wherein the wire structure is formed by welding tubular shaped wire sections together and the exterior surface of the wire structure is defined by the welded wire sections;

wherein the device is longitudinally flexible, the flexibility being such that it is greater than a delivery catheter to deliver the device into the bodily vessel; and

wherein the longitudinal flexibility of the device is defined by deflection of the device from a neutral line to 1mm when there is a force less then 8 grams.

~~26~~20. The device according to claim ~~25~~19, wherein the welding is laser welding.

~~27~~21. A delivery system for inserting a device an implantable medical device according to claim 1, within a bodily vessel, wherein the device is expandable by balloon inflation, the delivery system comprising a balloon delivery catheter and the device, wherein the expandable medical device is mounted onto the balloon of the delivery catheter.

~~28~~22. A delivery system for inserting an implantable medical device according to claim 1, within a bodily vessel, wherein the device is self-expandable, the delivery system comprising a delivery catheter and the device, wherein the device is mounted onto a distal portion of the delivery catheter.

~~29~~23. The device according to ~~claim 1 or~~ claim ~~25~~19, wherein the device is deployed at a pressure equal to or below 4atm.

~~30. The device according to claim 1 or claim 25, wherein the device is longitudinally flexible, the flexibility being such that it is greater than a delivery catheter to deliver the device into the bodily vessel.~~

~~31. The device according to claim 30, wherein the longitudinal flexibility of the device is defined by deflection of the device from a neutral line to 1mm when there is a force less then 8 grams.~~

~~32~~24. The device according to ~~claim 1 or~~ claim ~~25~~19, wherein the structure of the device provides a normalized radial force 18 to 19grams per mm of length.

~~33~~25. The device according to claim ~~32~~24, wherein the structural support of the device provides 3 to 4% of deflection of the structure of the device together with natural pulsing of an intracranial vessel wall.

~~34~~26. The device according to ~~claim 1 or~~ claim ~~25~~19, wherein the device has a profile in a compressed delivery form of 0.020 inches.

~~35~~27. The device according to ~~claim 1 or~~ claim ~~25~~19, wherein the device has a profile between 0.014 to 0.016 inches and the profile of the device in an uncompressed delivery form is between 0.020 to 0.022 inches.

~~36~~28. The device according to ~~claim 1 or~~ claim ~~25~~19, wherein the device has uniform material distribution and wall coverage for providing support to a bodily vessel.

~~37~~29. The device according to claim ~~36~~18, wherein the ratio of the material is in the range of 12 to 16%, the range being dependent on the diameter of deployment.

~~38~~30. The device according to ~~claim 1 or~~ claim ~~25~~19, wherein the device comprises struts, the struts having a thickness and width less than or equal to 0.0028 inches.

~~39~~31. The device according to ~~claim 1 or~~ claim ~~25~~19, wherein the device has a surface to length ratio between 1.1 to 1.3mm²/mm to provide minimal vessel injury score.